Self-Administered Drug(s) (SAD)

Guideline Number: MPG280.08
Approval Date: April 14, 2021

➲ Terms and Conditions

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Policy Summary

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Overview

The Centers for Medicare and Medicaid Services (CMS) publishes guidelines instructing UnitedHealthcare to develop a process to determine whether a drug or biological is usually self-administered and excluded from payment. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually administered by the patients who take them. Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals
- They are of the type that are not usually self-administered
- They meet all the general requirements for coverage of items as incident to a physician's service
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administering according to accepted standards of medical practice
- They are not excluded as Noncovered immunizations
- They have not been determined by the FDA to be less than effective

Medicare Part B generally does not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs.

Guidelines

UnitedHealthcare makes its own individual determination on each drug. UnitedHealthcare will continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. If a drug is available in both oral and injectable form, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

The following factors are considered when making decisions regarding the "self-administered" status of a drug when data is not available.

Route of Administration

- Drugs delivered intravenously are presumed to be not usually self-administered
- Drugs injected intramuscularly are presumed to be not usually self-administered, although depth and nature of the drug may be considered
- Drugs delivered subcutaneously are considered to be usually self-administered
- Drugs delivered by other routes of administration such as oral, suppositories, and topical medications are all considered to be usually self-administered

Status of Condition

- Acute: a condition that is likely to be of short duration and/or the expected course of treatment is for a short, finite interval (usually less than 2 weeks).
- Chronic: a condition that is expected to last longer than 2 weeks

Frequency of Administration

- Infrequent Injection: e.g., drug given monthly or less than once a month
- Frequent Injection: e.g., drug given one or more times per week or more than once per month

In arriving at a single determination as to whether a drug is usually self-administered, UnitedHealthcare will make a separate determination for each indication for a drug as to whether that drug is usually self-administered. Contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

UnitedHealthcare considers the following types of evidence:

- Peer reviewed medical literature
- Standards of medical practice
- Evidence-based practice guidelines
- FDA approved label
- Package inserts
- Drug compendia references
- Self-administration utilization statistics

UnitedHealthcare may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Self-Administered Drug Process Flow

The process steps to determine whether a drug is self-administered are as follows:

- Determine if the drug is produced in parenteral form
- Determine the route of administration – if only administered IV, the drug is covered
- Determine if the route of administration is IM or SQ, and if the drug is administered in the outpatient setting, list the clinical indications and determine the percent of utilization by clinical indication
- Review claims data and check a variety of sources/factors to arrive at the preliminary recommendation:
    - Acute/chronic setting
    - Clinical indication
    - FDA/drug package inserts
    - Provider specialty
    - Estimate the % self-administered (greater than or less than 50%) by indication
    - Assess all information to determine whether the drug is covered under the benefit category and notify providers.

Route of Administration Modifier

The use of the JA and JB modifiers is required for drugs which have one HCPCS Level II (J or Q) code but multiple routes of administration. Drugs that fall under this category will be marked with an asterisk (*) and must be billed with JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug. Claims billed with the JA modifier are not part of the SAD exclusion. The Contractor will process claims with the JA modifier applying the policy that not

only the drug is medically reasonable and necessary, but also that the route of administration is medically reasonable and necessary. Claims for drugs marked with an asterisk (*) billed without a JA or JB modifier will be denied.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description	Brand Name	SAD Effective Date	SAD End Date
C9399	Unclassified Drugs or Biologicals	Abaloparatide (Tymlos®)	12/02/2019	
C9399	Unclassified Drugs or Biologicals	Abatacept SQ (Orencia®)	05/31/2017	
C9399	Unclassified Drugs or Biologicals	Adalimumab-adbm (Cyltezo)	12/02/2019	
C9399	Unclassified Drugs or Biologicals	Adalimumab-atto (Amjevita™)	12/15/2016	
C9399	Unclassified Drugs or Biologicals	Albiglutide for SQ injection (Tanzeum™)	12/01/2014	
C9399	Unclassified Drugs or Biologicals	Alirocumab (Praluent®)	11/15/2015	
C9399	Unclassified Drugs or Biologicals	Anakinra [Kineret™] 100 MG	07/01/2013	
C9399	Unclassified Drugs or Biologicals	Asfotase-alfa (Strensiq™)	02/15/2016	
C9399	Unclassified Drugs or Biologicals	Brodalumab (Siliq™)	08/07/2017	
C9399	Unclassified Drugs or Biologicals	Dulaglutide (Trulicity®)	08/15/2015	
C9399	Unclassified Drugs or Biologicals	Dupilumab (Dupixent®)	08/07/2017	
C9399	Unclassified Drugs or Biologicals	Erenumab-aooe (Aimovig)	12/02/2019	
C9399	Unclassified Drugs or Biologicals	Etanercept-SZZS (Erelzi)	10/17/2016	
C9399	Unclassified Drugs or Biologicals	Evolucumab (Repatha™)	11/24/2015	
C9399	Unclassified Drugs or Biologicals	Exenatide Injection [Byetta®, Bydureon®]	07/01/2013	
C9399	Unclassified Drugs or Biologicals	Galcanezumab-adbm (Emgality)	12/02/2019	
C9399	Unclassified Drugs or Biologicals	Golimumab [Simponi®]	10/17/2016	
C9399	Unclassified Drugs or Biologicals	Insulin glargine injection (Toujeo®, Toujeo SoloStar®)	06/15/2015	
C9399	Unclassified Drugs or Biologicals	Interferon beta 1a, 11 mcg Rebif®	01/01/2014	
C9399	Unclassified Drugs or Biologicals	Ixekizumab (Taltz™)	06/15/2016	
C9399	Unclassified Drugs or Biologicals	Liraglutide [Victoza®] (Saxenda®)	07/01/2013	
C9399	Unclassified Drugs or Biologicals	Methotrexate-Solution Auto-injector Non-Chemotherapeutic (Otrexup™, Rasuvo®)	08/15/2015	
C9399	Unclassified Drugs or Biologicals	Metreleptin for injection (Myalept™) 11mg	10/13/2014	

HCPCS Code	Description	Brand Name	SAD Effective Date	SAD End Date
C9399	Unclassified Drugs or Biologicals	Parathyroid hormone (Natpara®)	04/26/2015	
C9399	Unclassified Drugs or Biologicals	Peginterferon beta-1a (Plegridy™)	09/28/2015	
C9399	Unclassified Drugs or Biologicals	Peginterferon Alfa-2a [Pegasys®]	07/01/2013	
C9399	Unclassified Drugs or Biologicals	Peginterferon Alfa-2b [PegIntron®, Sylatron®, Redipen®]	07/01/2013	
C9399	Unclassified Drugs or Biologicals	Pegvisomant (Somavert®)	09/07/2013	
C9399	Unclassified Drugs or Biologicals	Pramlintide (Symlin®, SymlinPen 60, SymlinPen 120)	09/07/2013	
C9399	Unclassified Drugs or Biologicals	Quadmix (alprostadil, atropine, papaverine, phentolamine)	08/28/2017	
C9399	Unclassified Drugs or Biologicals	Sarilumab (Kevzara)	12/02/2019	
C9399	Unclassified Drugs or Biologicals	Secukinumab (Cosentyx™)	06/04/2015	
C9399	Unclassified Drugs or Biologicals	Semaglutide (Ozempic)	12/02/2019	
C9399	Unclassified Drugs or Biologicals	Sogroya® (somapacitan-beco)	04/05/2021	
C9399	Unclassified Drugs or Biologicals	Tesamorelin (Egrifta™)	06/04/2011	
C9399	Unclassified Drugs or Biologicals	Trimix: alprostadil, papaverine and phentolamine	03/17/2016	
*J0129	Injection, abatacept, 10 mg	Orencia®	04/05/2021	
J0135	Injection, Adalimumab, 20 MG	Humira™	07/11/2008	
J0270	Injection, Alprostadil, 1.25 MCG	Alprostadil®, Caverject®, Edex®, Prostin VR Pediatric®	07/01/2013	
*J0490	Injection, belimumab, 10 mg	Benlysta®	07/20/2019	
J0593	Injection, lanadelumab-flyo, 1 mg	Takhzyro®	12/02/2019	
J0599	Injection, C-1 esterase inhibitor (human), (Haegarda), 10 units	Haegarda®	01/01/2019	
J0800	Injection, corticotropin, up to 40 units	H.P. Acthar® Gel	04/05/2021	
J1324	Injection, Enfuvirtide, 1 MG	Fuzeon®	01/01/2007	
J1438	Injection, Etanercept, 25 MG	Enbrel® Enbrel Mini, Enbrel Sure Click, Brenzys. Also see	07/11/2008	
J1558	Injection, immune globulin, 100 mg	Xembify	03/27/21	
J1595	Injection, Glatiramer Acetate, 20 MG	Copaxone®, Glatopa®	07/11/2008	
J1675	Injection, Histrelin Acetate, 10 MCG	Supprelin®	01/01/2006	
J1744	Injection, Icatibant, 1 MG	Icatibant [Firazyr®]	07/01/2013	

HCPCS Code	Description	Brand Name	SAD Effective Date	SAD End Date
J1815	Injection, Insulin, Per 5 Units	Regular, NPH, Lente, Ultralente, Humalog, Humulin, Iletin, Insulin Lispro, Novo Nordisk, Pork Insulin, Ultralente, Velosulin, Humulin R, Iletin Ii, Insulin Purified Pork, ReliOn, Lente Iletin I, Novolin R, Humulin R U-500, Lantus, Lantus SoloStar, Novolog	07/11/2008	
J1826	Injection, interferon beta-1a, 30 mcg	Rebif®, Rebif Rebidose® Avonex Pen®	05/31/2017	
J1830	Injection Interferon Beta-1b, 0.25 MG	Betaseron® Extavia®	07/11/2008	
J2170	Injection, Mecasermin, 1 MG	Increlex® Iplex™	01/01/2007	
J2212	Injection, Methylnaltrexone, 0.1 MG	Relistor®	01/01/2013	
*J2354	Injection, Octreotide, Non-Depot Form for Subcutaneous or Intravenous Injection, 25 MCG	Octreotide Acetate Sandostatin®	07/11/2008	
J2440	Injection, Papaverine HCl, Up To 60 MG	Papaverine (generic)	03/15/2003	
J2941	Injection, Somatropin, 1 MG	Genotropin® Nutropin® Humatrope® Norditropin® Nutropin® Genotropin® Saizen® Serostim® Biotropin® Genotropin-MiniQuick® Nutropin Aq® Omnitrope® Saizen Somatropin RDNA Origin® Serostim RDNA Origin® Zorbtive®, Accretropin™	07/11/2008	
J3030	Injection, Sumatriptan Succinate, 6 MG	Imitrex®, Imitrex Statdose Pen®, Zembrace™, SymTouch™, Alsuma, Sumavel® DosePro®	07/11/2008	
J3031	Injection, fremanezumab-vfrm, 1 mg	Ajovy®	10/01/2019	
J3110	Injection, Teriparatide, 10 MCG	Forteo®	07/11/2008	
J3355	Injection, Urofollitropin, 75 Iu	Fertinex® Metrodin® Follistim® Gonal-F® Bravelle®	01/01/2006	

HCPCS Code	Description	Brand Name	SAD Effective Date	SAD End Date
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Abaloparatide (Tymlos®)	09/28/2018	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Abatacept SQ (Orencia®)	11/20/2013	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Adalimumab-adbm (Cyltezo®)	09/28/2018	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Adalimumab-adaz (Hyrimoz®)	09/09/2019	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Adalimumab-atto (Amjevita™)	12/15/2016	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Adalimumab-bwwd (Hadlima®)	09/09/2019	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Albiglutide (Tanzeum®)	10/22/2014	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Alirocumab (Praluent®)	07/24/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Anakinra (Kineret®)	07/11/2008	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Asfotase alfa (Strensiq™)	02/15/2016	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Becaplermin (Regranex®)	04/27/2006	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Brodalumab (Siliq™)	07/16/2017	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Cortocotropin (H.P Acthar Gel™)	11/20/2013	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Dulaglutide (Trulicity™)	06/01/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Dupilumab (Dupixent®)	07/16/2017	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Erenumab-aoooe (Aimovig®)	09/18/2019	

HCPCS Code	Description	Brand Name	SAD Effective Date	SAD End Date
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Etanercept-SZZS (Erelzi)	10/17/2016	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Evolocumab (Repatha™)	08/27/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Exenatide Injection (Byetta®, Bydureon®)	01/01/2007	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Galcanezumab-gnlm (Emgality®)	09/18/2019	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Golimumab (Simponi®)	10/17/2016	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Insulin Glargine Injection (Toujeo®,Toujeo SoloStar®)	06/01/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Interferon beta 1a, (Rebif®)	06/04/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Ixekizumab (Taltz™)	06/15/2016	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Liraglutide-GLP-1 (Victoza®) (Saxenda®)	05/01/2010	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Methotrexate-Solution Auto-injector Non-Chemotherapeutic (Otrexup™, Rasuvo®)	06/01/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Metreleptin for injection (Myalept™) 11mg	10/13/2014	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Mipomersen Sodium (Kynamro®)	07/01/2013	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Parathyroid hormone (Natpara®)	04/15/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Peginterferon Alfa 2-A (Pegasys®)	01/01/2007	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Peginterferon, Alfa 2-B, (Pegylated Interferon Alfa-2b, PegIntron®, Sylatron®, Redipen®)	03/15/2003	

HCPCS Code	Description	Brand Name	SAD Effective Date	SAD End Date
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Peginterferon beta-1a (Plegridy™)	09/28/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Pegvisomant (Somavert®)	07/16/2007	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Pramlintide Acetate (Symlin®, SymlinPen 60, SymlinPen 120)	01/01/2007	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Quadmix (alprostadil, atropine, papaverine, phentolamine)	05/31/2017	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Risankizumabrzaa (Skyrizi™)	01/12/2020	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Sarilumab (Kevzara®)	09/18/2019	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Secukinumab (Cosentyx™)	01/21/2015	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Semaglutide (Ozempic®)	09/18/2019	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Sogroya® (somapacitan-beco)	04/05/2021	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Tesamorelin (Egrifta™)	07/01/2013	
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Tocilizumab (Actemra®)	07/03/2017	07/15/2020
J3490/ J3590/J9999	Unclassified Drugs/Unclassified Biologics/Not otherwise classified, antineoplastic drugs	Trimix: (alprostadil, papaverine and phentolamine)	08/15/2010	
J7999	Compounded drug, not otherwise classified	Quadmix (alprostadil, atropine, papaverine, phentolamine)	03/17/2017	
J7999	Compounded drug, not otherwise classified	Trimix: alprostadil, papaverine and phentolamine	01/01/2016	
J9216	Injection, Interferon, Gamma 1-B, 3 Million Units	Actimmune®	07/11/2008	
J9218	Leuprolide Acetate, Per 1 MG	Lupron®, Eligard®	03/15/2003	
Q3027	Injection, interferon beta-1a, 1 mcg for intramuscular use	Avonex®	01/01/2014	

HCPCS Code	Description	Brand Name	SAD Effective Date	SAD End Date
Q3028	Injection, interferon beta-1a, 1 mcg for subcutaneous use	Rebif®	01/01/2014	

Modifier	Description
JA	Administered intravenously
JB	Administered subcutaneously

Revenue Code	Description
0637	Self-administered drugs (Use this revenue code for self-administered drugs not requiring detailed coding)

Definitions

Administered: the term administered refers to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Only injectable (including intravenous) drugs are eligible for inclusion under the "incident to" benefit.

Apparent on its Face: For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

By the Patient: The term "by the patient" means Medicare benificiaries as a collective whole, the patients themselves, and not other individuals who may assist with the administration of the drug. The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by UnitedHealthcare members for medically necessary indications. UnitedHealthcare ignores all instances when the drug is administered on an inpatient basis.

Usually: For the purpose of appling this exclusion, the term "usually" means more than 50 percent of the time for all Medicare benificiaries, who use the drug regardless of the indication or routeof administration.

Questions and Answers

1	Q:	What if a member wants to appeal the denial of a self-administered drug?
	A:	If a member's claim for a particular drug is denied because the drug is subject to the "self-administered drug" exclusion, the member may appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an advance notification of denial is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the member for an excluded drug.

2	Q:	How often will M&R review the list of self-administered drugs?
	A:	CMS expects that review of injectable drugs will be performed on a rolling basis and no less frequently than annually.
3	Q:	What does “incident to” mean?
	A:	The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished "incident-to" a physician's service provided that the drugs are not “usually self-administered” by the patient. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA), amended §§1861(s)(2)(A) and 1861(s)(2)(B) of the Social Security Act (SSA) to redefine this exclusion. The prior statutory language referred to those drugs "which cannot be self-administered by the patient.” Implementation of the BIPA provision requires interpretation of the phrase "not usually self-administered” by the patient.

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A52571 Self-Administered Drug Exclusion List	First Coast	FL, PR, VI	FL, PR, VI
N/A	A53032 Self-Administered Drug Exclusion List	Noridian	AS, CA (Entire State), GU, HI, MP, NV	AS, CA (Northern and Southern), GU, HI, MP, NV
N/A	A53033 Self-Administered Drug Exclusion List	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A53127 Self-Administered Drug Exclusion List	Novitas	AR, CO, DC, DE, LA, MD, NM, MS, NJ, OK, PA, TX	AR, CO, DC, DE, LA, MD, NM, MS, NJ, OK, PA, TX
N/A	A52800 Self-Administered Drug Exclusion List: (SAD List)	WPS	AK, AL, AR, AZ, CA (Entire State), CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO (Entire State), MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, KS, MO, NE, IN, MI
N/A	A53021 Self-Administered Drug Exclusion List: Medical Policy Article	NGS	CT, IL, MA, ME, MN, NH, NY (Entire State), RI, VT, WI	CT, IL, MA, ME, MN, NH, NY (Upstate, Downstate, Queens), RI, VT, WI
N/A	A53022 Self-Administered Drug Exclusion List: Medical Policy Article	NGS	IL, MN, WI	IL, MN, WI

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A52527 Self-Administered Drug Exclusion List: and Biologicals Excluded from Coverage-Medical Policy Article (R7)	CGS	KY, OH	KY, OH
N/A	A53066 Self-Administered Drug Exclusion List	Palmetto	AL, GA, TN, SC, VA, WV, NC	AL, GA, TN, SC, VA, WV, NC
N/A	A57501 Self-administered drug (SAD) list revision to the Part A and Part B article	First Coast	FL, PR, VI	FL, PR, VI
N/A	A55742 Self-administered drug (SAD) list revision to the Part A and Part B article	First Coast	FL, PR, VI	FL, PR, VI
N/A	A55898 Self-administered drug (SAD) list revision to the Part A and Part B article	First Coast	FL, PR, VI	FL, PR, VI
N/A	A54770 Self-administered drug (SAD) list Praluent® (alirocumab), repatha™ (evolocumab), and natpara® (parathyroid hormone) J3490/J3590/C9399	First Coast	FL, PR, VI	FL, PR, VI
N/A	A55330 Self-Administered drug (SAD) list revision to the Part A and Part B article	First Coast	FL, PR, VI	FL, PR, VI
N/A	A56244 Self-administered drug (SAD) list revision to the Part A and Part B article	First Coast	FL, PR, VI	FL, PR, VI
N/A	A55019 Self-administered drug (SAD) list revision to the Part A and Part B article: asfotase alfa (Strensiq™) J3490/J3590/C9399	First Coast	FL, PR, VI	FL, PR, VI
N/A	A53020 Process for Determining Self-Administered Drug Exclusions-Medical Policy Article	NGS	CT, IL, MA, ME, MN, NH, NY (Entire State), RI, VT, WI	CT, IL, MA, ME, MN, NH, NY (Upstate, Downstate, Queens), RI, VT, WI
N/A	A52535 Process for Determining Self-Administered Drug Exclusions-Medical Policy Article	CGS	KY, OH	KY, OH
N/A	A53893 Self-Administered Drugs-Process to Determine Which Drugs Are Not Usually Self-administered By the Patient	Noridian	AS, CA (Entire State), GU, HI, MP, NV	AS, CA (Northern and Southern), GU, HI, MP, NV
N/A	A53034 Self-Administered Drugs-Process To Determine Which Drugs Are Usually Self-Administered by the Patient	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

LCD	Article	Contractor	HHH MAC
N/A	A52527 Self-Administered Drug Exclusion List: and Biologicals Excluded from Coverage-Medical Policy Article (R7)	CGS	CO, DC, DE, IA, KS, MD, MO, MT, ND, NE, PA, SD, UT, VA, WV, WY

CMS Benefit Policy Manual

Chapter 15; § 50 Drugs and Biologicals, § 50.2 Determining Self-Administration of Drug or Biological, §50.3 Incident to Requirements

CMS Claims Processing Manual

Chapter 1; § 60 Provider Billing of Non-covered Charges on Institutional Claims
Chapter 17; § 80.5 Self-Administered Drugs

MLN Matters

Article MM6950, Medicare Benefits Policy Manual Update–Determining Self-Administration of Drug or Biological

Other(s)

Noridian Self-Administered Drug Exclusion List-R18
Medicare Intermediary Manual, Part 3 – Claims Process, Transmittal 1790, Dated March 2000.
Social Security Act:

- 1861(s)(2)(A), Medical and Other Health Service
- 1861(s)(2)(B), Medical and Other Health Service
- First Coast Self-Administered Drug billing guidance
- CGS Process to Determine Which Drugs Are Not Usually Self-administered by the Patient

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes

04/14/2021	**Policy Summary**
	Guidelines
	• Removed language indicating:
	  ○ We are instructed to follow the instructions [in the policy] below when applying the exclusion for drugs that are usually self-administered by the patient
	  ○ For certain injectable drugs, it is apparent that due to the nature of the condition(s) for which they are self-administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered
	Status of Condition
	• Revised language to indicate:
	  ○ Acute: A condition that is likely to be of short duration and/or the expected course of treatment is for a short, finite interval (usually less than 2 weeks)
	  ○ Chronic: A condition that is expected to last longer than 2 weeks
	Frequency of Administration
	• Removed language defining the terms “administered” and “usually” (refer to the *Definitions* section)
	Route of Administration Modifier *(new to policy)*
	• Added language to indicate the use of the JA and JB modifiers is required for drugs which have one HCPCS Level II (J or Q) code but multiple routes of administration

Date	Summary of Changes
	○ Drugs that fall under this category will be marked with an asterisk (*) and must be billed with JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug ○ Claims billed with the JA modifier are not part of the SAD exclusion ○ The Contractor will process claims with the JA modifier applying the policy that not only the drug is medically reasonable and necessary, but also that the route of administration is medically reasonable and necessary ○ Claims for drugs marked with an asterisk (*) billed without a JA or JB modifier will be denied **Applicable Codes** *HCPCS Codes* • Added C9399, J0129, J0800, and J1558 • Updated list of applicable brand names for: ○ J2354; added Octreotide Acetate ○ J3490, J3590, and J9999: ▪ Added Sogroya® (somapacitan-beco) ▪ Removed Pasireotide Diaspartate (Signifor) ○ J1438; removed instruction to refer to J3590/Etanercept-szzs (Erelzi) *Modifier Codes* • Added JA and JB **Definitions** • Added definition of "Administered" • Updated definition of: ○ By the Patient (*previously listed as "Self-Administered by the Patient")* ○ Usually (*previously listed as "Usually Self-Administered"*) **Questions and Answers (Q&A)** • Updated Q&A #3 addressing outpatient drugs that are "incident to" a physician's service **Supporting Information** • Archived previous policy version MPG280.07

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.